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Appl. No	:	10/553,736	TC/A.U.	:	1797
Applicant	:	Bedard et al.	Examiner	:	McKane, Elizabeth
Filed	:	September 21, 2006	Docket No.	:	BED001

Title : Ozone Sterilization Method

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

This paper is filed in response to the final Office Action dated March 21, 2008, accompanies a Notice of Appeal and is provided in connection with a Pre-Appeal Brief Request for Review of the rejections presented in the above-identified U.S. patent application. This Pre-Appeal Brief Request for Review basically concentrates on the following errors: 1) The teachings of Robitaille et al. and Hennebert et al. are not compatible; and 2) the Examiner has misinterpreted the teachings in the prior art.

I. GENERAL OVERVIEW

A. The Rejection

Just concentrating on independent claims 1 and 6, the Examiner appears to be of the opinion that Robitaille et al. discloses all the limitations of these claims except Robitaille et al. does not disclose removing condensation after a first sterilization cycle and prior to a second sterilization cycle as claimed. The Examiner attempts to address this deficiency by noting that Hennebert et al. teaches avoiding problems due to water condensation by automatically purging condensate during sterilization (citing column 2, lines 1-6). As the full positions taken by the Examiner were not considered to be clear and comments made in the Advisory Action raised further questions, an interview after final was conducted with the Examiner. During the

interview, the Examiner explained that Robitaille et al. was being relied upon to disclose an entire cycle through steps 1-12 in Figure 3 and that Hennebert et al. was seen to teach purging or flushing a sterilization chamber through an entire cycle. With this in mind, she held that it would be obvious to purge throughout all of steps 1-12 of Figure 3 of Robitaille et al. and this overall purging would inherently result in purging between the sub-cycles of steps 4-7. As will be detailed more fully below, these positions are contrary to what would be suggested to one of ordinary skill in the art and actually disclosed by the prior art.

B. Robitaille et al.

The Robitaille et al. reference deals with ozone sterilization methods. When considered against conventional sterilization methods, ozone sterilization is considered to show the most promise as a quick, effective and safe sterilization procedure. However, according to the Robitaille et al. disclosure, using ozone alone is not reliable. Therefore, in order to achieve reliable sterilization, it is known that there must be water present and, in particular, a high humidity level. See paragraph 0006 of Robitaille et al. As discussed in Robitaille et al., even the extremely high humidity level of 85% is not consistently reliable and a preferred humidity for reliability is above 90%, and preferably 100%. See paragraph 0016 of Robitaille et al. The Robitaille et al. reference represented a substantial breakthrough in realizing the potential of ozone sterilization coupled with the application of a reduced pressure step to provide an effective means to achieve the high humidity levels needed.

Certainly, Robitaille et al. is a good starting place for the present invention. As such, Robitaille et al. sets forth, as can best be seen in Figure 3, a method for ozone sterilization. By comparing Figure 1 of the subject application to Figure 3 of Robitaille et al., one can clearly see that vacuum step 101 is analogous to vacuum step 4; humidification step 102 is analogous to humidifying step 5; ozone injection step 103 is analogous to ozone fill step 6; humidified ozone exposure/sterilization step 104 is analogous to ozone exposure step 7; and step 106, which repeats the sterilization cycle, is analogous to step 8 of Robitaille et al. However, the inclusion of a reconditioning step 105 provided after step 104 in accordance with the present invention, wherein the chamber is flushed with an inert gas, is not in Robitaille et al.

C. Hennebert et al.

Hennebert et al.is essentially concerned with formaldehyde sterilization. Although the Hennebert et al. indicates the possibility of other sterilization agents, no other agents are detailed. Every reference in Hennebert et al. refers to formaldehyde. In the formaldehyde sterilization process of Hennebert et al., steam is used as a form of heat or temperature control. That is, formaldehyde sterilization can be effective under dry conditions, but the temperature must be initially raised such that Hennebert et al. teaches that the purpose of the steam is simply to increase the temperature. See column 8, lines 16-18 stating, "[s]team flow is controlled by valve 18, which is regulated so that the temperature in chamber 1 reaches the chosen sterilization temperature." Further, a drying step is taught to be before a sterilization step. Note steps 1-8 of Example 1, column 10, lines 45-59. The drying step is completed before the sterilization step because the water would interfere with sterilization.

II) The teachings of Robitaille et al. and Hennebert et al. are not compatible.

Simply put, one would not look to the formaldehyde sterilization of Hennebert et al. to modify the ozone sterilization system of Robitaille et al.. With Robitaille et al., the humidity is carefully controlled and kept at extremely high values for the ozone sterilization. Hennebert et al. employs steam for initial heating, but then the steam must be removed before sterilization because the water would interfere with sterilization. Therefore, these two types of sterilization are directly opposite on this point. There is absolutely no equivalent in formaldehyde sterilization to the careful control of humidity which is required in the ozone sterilization of the invention. Thus, a person skilled in the art, looking for a solution in an ozone sterilization process, would have no reason to look for answers in formaldehyde sterilization. In addition, removing steam and condensate throughout the entire cycle of Robitaille et al. as suggested by the Examiner is directly contrary to the desire of Robitaille et al. to basically maintain the highest level of humidity possible. Therefore, this combination would destroy the teachings in Robitaille et al.

III) **The sterilization cycle in Hennebert et al. is not analogous to the overall sterilization cycle in Robitaille et al.; Hennebert et al. does not teach withdrawing condensed water throughout an entire sterilization cycle; and Neither Robitaille et al. nor Hennebert et al. teach or suggest purging condensed water from the sterilization chamber between sterilization cycles.**

Hennebert et al. reference cannot be reasonably read to include an overall sterilization cycle such as steps 1-12 shown in the Robitaille et al. reference. For example, with reference to column 3, lines 4-46, the process of Hennebert et al. is explained. The various steps will be discussed in relation to the steps 1-12 shown in Figure 3 of Robitaille et al. Hennebert et al. first teaches the material or article to be sterilized is introduced into the chamber analogous to step 1. See column 3, lines 6+. The chamber is brought to a first sub-atmospheric pressure analogous to step 4. Next, steam is introduced producing an increase in pressure at a temperature which is equal or close to which the material or the article is to be brought until the intended temperature is obtained, while a partial suction of steam and condensed water out of the chamber is continuously carried out. This step is generally analogous to step 5. Therefore, **it is only during step 5 wherein partial suction of steam and condensed water out of the chamber is continuously carried out.** The admission of steam is then interrupted and the chamber is brought to reduced pressure until the water which condenses during the injection of steam disappears. Following that step, numerous additional steps are presented, none of which include removing condensed water or repeating other steps. In a final step, the material or article is withdrawn.

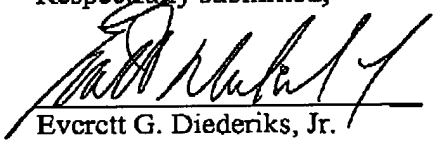
Since the removal of condensed water out of the chamber is not conducted throughout the entire cycle in Hennebert et al., this reference cannot be used to support removing condensed water between cycles. Note that it is only during the admission of steam step that the partial suction of steam and condensed water out of the chamber is continuously produced. That is, steam is introduced to achieve the desired temperature and then the steam and condensed water are removed in a single step of an overall cycle. It is not during the entire cycle. More support for this position can be found in column 8 describing the operation of vacuum pump 6. During operation of the device, steam flow is controlled by valve 18, which is regulated so that the temperature in chamber 1 reaches a chosen sterilization temperature. Evacuation of the gas is

present in the chamber and simultaneously carried out by vacuum pump 6. After the chosen time, the admission of steam is cut automatically by closing valve 18, while pump 6 continues to operate for a pre-programmed time. Pressure in chamber 1 reaches a low value. The load is hot and dry at that time, the operation of the vacuum pump is interrupted automatically and valve 8 is closed. (Of course, as stated above, using such a step before ozone sterilization would render the ozone sterilization entirely ineffective.) Subsequent to that, valves 29 and 32 of the sterilization agent generator are opened. This portion of the Hennebert et al. reference clearly shows that water condensation is not removed throughout a single sub-cycle, let along throughout an entire sterilization cycle, but rather it is removed just before the addition of the formaldehyde. As such, Hennebert et al. cannot be used for the proposition that removal of condensate would occur after a first sterilization cycle and prior to a second sterilization cycle as required by claim 1 or between the first and second cycles as set forth in claim 6.

IV. CONCLUSION

Because Robitaille et al. mandates an extremely high humidity environment for sterilization and Hennebert et al. specifically teaches to remove water and create a dry climate for sterilization, the references are not compatible. In addition, Hennebert et al. does not teach removing water throughout an entire sterilization cycle as proposed by the Examiner. Based on the clear errors identified above, it is submitted that the rejections should be withdrawn, the claims allowed and the application passed to issue.

Respectfully submitted,



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